Appendix F : Summary of Safety and Effectiveness Data

NOV 0 7 2001

K011174

I. General Information

Company :	Fotona d.d. Stegne 7, 1210 Ljubljana United Kingdom
Contact Person :	Mojca Valjavec
Preparation Date :	04-05-01
Device Trade Name :	Paradigm-Fotona PEROVSKITE Nd:YAP Laser System and Accessories
Common Name :	Nd:YAP Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48

II. Description

The Paradigm-Fotona PEROVSKITE system is based on Nd:YAP laser technology. Within the system, an optical cavity contains the Nd:YAP crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

II. Intended Use

The Paradigm-Fotona PEROVSKITE Nd:YAP Laser System is indicated for the removal of unwanted hair in Fitzpatrick skin types I - VI.

III. Summary of Substantial Equivalence

Fotona believes that its PEROVSKITE system is substantially equivalent to the Laserscope Lyra, Altus Medical Aesthetic Nd:YAG Laser and Depilase YAGLASE Nd:YAG laser all three previously cleared for the removal of unwanted hair.

Technologically, the predicate device has completely identical characteristics to the YAPLASE, except the laser rod. Both systems comprising a flashlamp pumped laser rod (either Nd:YAG or Nd:YAP) generating light at a wavelength of 1064 nm (Nd:YAG) or 1079 nm (Nd:YAP), which is subsequently delivered to the patient via an optical fiber delivery system and focusing handpiece.

The PEROVSKITE Laser output characteristics are identical to those of predicate device.

All lasers are microprocessor controlled devices.

All lasers utilize class I aiming beams which pose no hazard to the user.

All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the Paradigm-Fotona PEROVSKITE are comparable to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Mojca Valjavec, Dipl. Eng.
Marketing and Sales
Fotona d.d.
Stegne 7 1210 Ljubljana
Slovenia

Re: K011174
Trade/Device Name: Paradigm-Fotona PEROVSKITE Nd:YAP Laser System and Accessories
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: August 7, 2001
Received: August 9, 2001

Dear Mr. Valjavec:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 7 2001

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011174

Device Name: **Paradigm-Fotona PEROVSKITE Nd:YAP Laser System and Accessories**

Indications For Use:

The Paradigm-Fotona PEROVSKITE Nd:YAP Laser System and Accessories are intended for the removal of unwanted hair in Fitzpatrick skin types I - VI.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Well

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

K011174

Prescription Use ✓
(Per 21 CFR 801.109)

OR 510(k) Number ~~Over-The-Counter Use~~